

VETERINARY MEDICINE BOARD[811]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code section 169.5, the Board of Veterinary Medicine hereby gives Notice of Intended Action to amend Chapter 1, “Description of Organization and Definitions,” and Chapter 12, “Standards of Practice,” Iowa Administrative Code.

The proposed amendments revise veterinary standards of practice in Chapter 12 by expanding the current veterinary requirements for the prescription of drugs and controlled substances and the storage and dispensing of controlled substances. In addition, the proposed amendments provide additional veterinary requirements for the use of diagnostic imaging, administration of anesthesia, safety and sanitation in veterinary facilities, proper disposal of waste materials, use of sterile surgical equipment, veterinary facility standards, and veterinary practice record keeping.

Any interested person may make written suggestions or comments on the proposed amendments on or before April 8, 2014. Written comments should be addressed to Dr. David Schmitt, State Veterinarian, Wallace State Office Building, 502 E. 9th Street, Des Moines, Iowa 50319. Comments may be submitted by fax to (515)281-4282 or by e-mail to David.Schmitt@IowaAgriculture.gov.

The proposed amendments are subject to the Board’s general waiver provision.

After analysis and review of this rule making, no adverse impact on jobs has been found.

These amendments are intended to implement Iowa Code chapters 169 and 272C.

The following amendments are proposed.

ITEM 1. Adopt the following **new** definitions in rule **811—1.4(17A,169)**:

“*Client*” means the patient’s owner, owner’s designee, or other person responsible for the patient.

“*Client consent*” requires that the veterinarian inform the client of the reasonable and usual diagnostic and treatment options available and provide an assessment of the risks and benefits of such choices, the prognosis and an estimate of the fees expected for the provision of services. The consent of the client shall be provided in verbal or written form prior to initiation of diagnostic and treatment procedures and shall be documented in the medical record by the veterinarian or staff. The client shall indicate that the client’s questions have been answered to the client’s satisfaction and that the client consents to the recommended treatments or procedures.

“*Patient*” means an animal or group of animals examined or treated by a veterinarian.

ITEM 2. Amend rule 811—12.1(169) as follows:

811—12.1(169) Prescription drugs and restricted immunization products Veterinary practice standards. ~~A drug or immunization product intended for veterinary use where state or federal law restricts this drug or immunizing product to use by or under the order of a licensed veterinarian, shall only be sold or distributed to, or on the order of, a licensed veterinarian, to be used in the course of the veterinarian’s professional practice.~~

~~**12.1(1)** The order for all such drugs or immunizing products shall be accompanied by the veterinarian’s original prescription which should show the quantity of the product, the number of times the prescription can be refilled, the veterinarian’s name, address and telephone.~~

~~**12.1(2)** A prescription veterinary product shall not be deemed to be used “in the course of the veterinarian’s professional practice” unless the veterinarian is supervising the use of the product or a veterinarian/client/patient relationship exists.~~

~~12.1(3)~~ **12.1(1)** The board shall determine, on a case-by-case basis, if a valid veterinarian/client/patient relationship exists. ~~The board may consider, among other items, the following criteria~~ This relationship shall be deemed to exist when all of the following criteria have been met:

a. The veterinarian has assumed the responsibility for making medical judgments regarding the health of the animal(s) patient and the need for medical treatment, and the client (~~owner or other caretaker~~) has agreed to follow the instructions of the veterinarian; ~~and when~~

b. ~~There is~~ The veterinarian has sufficient knowledge of the animal(s) by the veterinarian patient to initiate at least a general or preliminary diagnosis of the medical condition of the animal(s) patient. This Sufficient knowledge means that the veterinarian has recently seen and is personally acquainted with the ~~keeping and care of the animal(s) patient~~ by virtue of an examination of the animal(s); patient or by medically appropriate and timely visits to the premises where the animal(s) patient is kept; and ~~when~~

c. The ~~practicing~~ veterinarian is readily available or provides for follow-up in case of adverse reactions ~~of or failure of the regimen of therapy.~~

12.1(2) Both the veterinarian and the client have the right to establish or decline a valid veterinarian/client/patient relationship. Once the veterinarian and the client have agreed and entered into a relationship, and the veterinarian has begun patient care, the veterinarian may not neglect the patient and must continue to provide professional services related to the patient's injury or illness within the previously agreed limits. As subsequent needs and costs for patient care are identified, the veterinarian and client must confer and reach agreement on the continued care and responsibility for fees. If the informed client declines future care or declines to assume responsibility for the fees, the relationship may be terminated by either party.

12.1(3) If no ongoing medical condition exists, a veterinarian may terminate a valid veterinarian/client/patient relationship by notifying the client that the veterinarian no longer wishes to serve that patient and client. However, if an ongoing medical or surgical condition exists, the patient should be referred to another veterinarian for diagnosis, care, and treatment and the former attending veterinarian should continue to provide care as needed during the transition.

ITEM 3. Amend rule 811—12.2(169) as follows:

811—12.2(169) ~~Extra-label use of veterinary drugs and immunization products~~ Controlled substances, prescription medications and restricted immunization products. When state or federal law restricts a medication or immunization product intended for use by or on the order of a veterinarian, the veterinarian shall sell, distribute, or order the medication only in the course of the veterinarian's professional practice. A prescription veterinary medication or immunization product shall not be deemed to be used "in the course of the veterinarian's professional practice" unless a valid veterinarian/client/patient relationship exists.

12.2(1) *Prescriptions.* The order for all such medications or immunization products shall be accompanied by the veterinarian's original prescription that shows the following:

- a.* Veterinarian's name, address and telephone number;
- b.* Client's name;
- c.* Patient's name or identification;
- d.* Date issued;
- e.* Medication or product name, strength, and quantity;
- f.* Directions for use;
- g.* Number of times the prescription may be refilled;
- h.* Expiration date of the medication or product; and
- i.* Applicable withdrawal period (paragraph 12.2(2) "d") for livestock and poultry.

12.2(2) *Extra-label use of veterinary drugs and immunization products.* Any extra-label use of veterinary drugs and immunization products shall be by or under the order of a licensed veterinarian only and shall be subject to the following criteria:

~~12.2(1)~~ a. There shall be a veterinarian-/client-/patient relationship as defined in subrule 12.1(3) 12.1(1).

~~12.2(2)~~ b. For ~~drugs~~ medications used in ~~animals~~ patients not intended for food, one of the following applies:

(1) ~~there~~ There are no marketed ~~drugs~~ medications and immunization products specifically labeled for the ~~conditions~~ condition(s) diagnosed;

(2) The approved product is clinically ineffective; or

(3) ~~in~~ In the veterinarian's clinical judgment, the labeled dosage is inappropriate for the condition or the extra-label use should result in a better outcome for the patient.

~~12.2(3)~~ c. The health of the treated ~~animal(s)~~ patient is immediately threatened, and suffering or death would result from a failure to treat the affected ~~animal(s)~~ patient.

~~12.2(4)~~ d. Appropriate withdrawal ~~times~~ period shall be specified when the ~~veterinary~~ medications or immunization products are used in animals intended as food. Extra-label drug use in food-producing animals must follow Food and Drug Administration - Animal Medicinal Drug Use Clarification Act regulations (21 Code of Federal Regulations 530). Veterinarians are encouraged to consult the Food Animal Residue Avoidance Databank (FARAD) or public peer-reviewed documents when determining appropriate withdrawal period.

ITEM 4. Amend rule 811—12.3(169) as follows:

811—12.3(169) Prescription medication labeling and packaging. A ~~licensed~~ veterinarian shall comply with all of the following requirements for the storage, handling, dispensing, and administering of medication:

~~12.3(1)~~ The veterinarian shall maintain all controlled substances in compliance with state and federal requirements. All prescription medications and controlled substances must be purchased, maintained, handled, prescribed and dispensed in compliance with state and federal requirements including but not limited to the requirements of the Iowa board of pharmacy, the U.S. Occupational Safety and Health Administration, the U.S. Department of Agriculture, the U.S. Food and Drug Administration, the U.S. Environmental Protection Agency and the U.S. Drug Enforcement Agency. A valid veterinarian/client/patient relationship must be established before prescription medications may be dispensed or a prescription released. All medications administered, prescribed or dispensed must be documented in the patient's medical record. The sale of veterinary prescription medications or the extra-label use of any medication or product by a veterinarian without a valid veterinarian/client/patient relationship is not permissible.

~~12.3(2)~~ All medications that are dispensed from a container other than the original container shall be placed in a child-resistant container unless otherwise requested by the owner or unless the medication is in a form or size that cannot be easily dispensed in a child-resistant container.

~~12.3(3)~~ 12.3(2) All medications dispensed shall be labeled with the following information:

a. Name, telephone number, and address of the veterinary clinic, hospital, or service facility.

b. Name of the prescribing licensed veterinarian.

c. Date on which the prescription is dispensed.

d. Directions for use, including any cautionary statements and withdrawal times when appropriate.

e. ~~Name and species~~ Species of the patient.

f. Name, or identification, or location of the patient.

~~f.~~ g. Name of the owner.

~~g.~~ h. Name, strength, and dosage form of the medication. If the medication is a compounded product, all active ingredients must be listed on the label, with corresponding strengths or concentrations of each ingredient.

~~h.~~ i. Number of units dispensed.

~~i.~~ j. Expiration date. If the medication is a compounded product with no assigned expiration date, the veterinarian shall determine a beyond-use date as supported by the literature or by the veterinarian's professional judgment when no such supportive information exists.

~~j. k.~~ Appropriate withdrawal times period for livestock or poultry, when the animal patient or its product is intended as food.

~~12.3(4)~~ **12.3(3)** All medications dispensed in the original container shall retain the original label and, in addition, shall be labeled with the same information as required in subrule ~~12.3(3)~~ **12.3(2)**.

12.3(4) All medications that are dispensed in a container other than the original container shall be placed in a tamper-resistant container unless otherwise requested by the owner or unless the medication is in a form or size that cannot be easily dispensed in a tamper-resistant container.

12.3(5) Medications which have expired shall be removed from current inventory and shall not be dispensed or sold. Expired medications shall be disposed of in accordance with local, state and federal regulations.

12.3(6) Medications shall be dispensed only for specific animals and for specific veterinary medical therapies with the exception of groups of similar animals and other groups such as pet fish, kennels, and catteries for which dispensing shall be done judiciously within a valid veterinarian-/client-/patient relationship.

ITEM 5. Adopt the following **new** rules 811—12.4(169) and 811—12.5(169):

811—12.4(169) Veterinary medical records.

12.4(1) *Controlled substances records.* The veterinarian must maintain a controlled substance log which contains complete, accurate and readily retrievable records of all controlled substances possessed, administered, or dispensed.

a. Each record of a controlled substance which is dispensed must meet all U.S. Drug Enforcement Administration and Iowa board of pharmacy regulations for the controlled substances log.

b. Each log record must include the following information:

- (1) Name or identification of the patient.
- (2) Client's name and address, if not readily available from the veterinarian's records.
- (3) Name, strength and quantity of the controlled substance dispensed.
- (4) Date on which the controlled substance was dispensed.
- (5) Initials of the dispensing veterinarian or authorized auxiliary.
- (6) Name of the prescribing veterinarian.

c. All controlled substances must be kept in a locked storage area, and access to the storage area must be restricted pursuant to state and federal laws and regulations.

d. Each package or container in which a controlled substance is stored or dispensed must be clearly labeled pursuant to the requirements set forth in state and federal laws and regulations.

e. Each package or container in which a controlled substance is stored or dispensed must comply with all state and federal packaging requirements and with rule 811—12.2(169).

12.4(2) *Patient records.* Veterinary medical records are an integral part of veterinary care. Medical records are the property of the veterinarian, the practice and/or the practice owner. Each veterinarian shall maintain for at least five years an easily retrievable record for each patient that receives veterinary services. The record must be available for inspection by the client during normal business hours. The information within veterinary medical records is privileged and confidential and shall not be released except by court order, a public health emergency or consent of the client. The veterinarian in charge shall provide a copy of the complete record to the client not later than two business days after the veterinarian or practice receives from the client a request for the record. A veterinarian or veterinary practice may have an additional three business days to provide a copy of nondigital diagnostic images. The veterinarian may charge reasonable and customary fees for the copying of records.

a. Records required for patients defined as "livestock" in Iowa Code section 717.1(4) include the following:

- (1) Name, address and telephone number of the client.
- (2) Name or identity of the patient, pen, herd, flock, or group, including the identification number, if any.
- (3) Date of service.
- (4) Documentation of client consent.

- (5) Diagnosis or condition at the beginning of treatment of the patient, including results of tests.
- (6) Procedures/indications.
- (7) Name of medication and treatment administered indicating dosage, frequency and route of administration.
- (8) Withdrawal period.
- (9) Record of diagnostic images taken.
- (10) Name of attending veterinarian.
- b.* Records required for other patients include the following:
 - (1) Name, address and telephone number of the client.
 - (2) Name and identity of the patient, including the identification number, if any.
 - (3) Date of birth (or estimated age), sex, species and breed of patient.
 - (4) Dates of care, custody or treatment of the patient.
 - (5) A history of the patient's condition as it pertains to the patient's medical status.
 - (6) Documentation of client consent.
 - (7) Diagnosis or condition at the beginning of treatment of the patient, including results of tests and body weight.
 - (8) Surgery record, including preanesthesia medication, anesthesia, and the procedure performed.
 - (9) Name of medication and treatment administered indicating dosage, frequency and route of administration.
 - (10) Progress and disposition of the case.
 - (11) Record of diagnostic images taken.
 - (12) Name of attending veterinarian.

12.4(3) *Diagnostic images.*

- a.* Each diagnostic image must be identified with the following information:
 - (1) The name of the veterinarian or facility that took the diagnostic image.
 - (2) The name or identifying number, or both, of the patient.
 - (3) The name of the client.
 - (4) The date on which the diagnostic image was taken.
 - (5) The anatomical orientation depicted by the diagnostic image.
- b.* Diagnostic images must be retained for at least five years.
- c.* A diagnostic image of the patient or a copy must be released, upon the written or verbal request, to another veterinarian who has the authorization of the client. Original diagnostic images shall be returned in a reasonable time.

12.4(4) *General anesthesia.* General anesthesia is a condition caused by the administration of a drug or combination of drugs sufficient to produce a state of unconsciousness or dissociation and blocked response to a given pain or alarming stimulus. The following standards relating to general anesthesia must be adhered to:

- a.* Within 12 hours prior to the administration of a general anesthetic, the patient must receive a physical examination, with the results noted in the patient's medical records.
- b.* The patient under general anesthesia must be under observation for a length of time appropriate to the species for the patient's safe recovery.
- c.* The veterinarian must provide a method of respiratory monitoring that may include observing the patient's chest movements, observing the rebreathing bag, or using a respirometer.
- d.* The veterinarian must provide a method of cardiac monitoring which may include the use of a stethoscope or electrocardiograph monitor.

811—12.5(169) *Veterinary facilities.*

12.5(1) *Facility standards.* The following standards shall apply to all facilities used by a veterinarian to provide veterinary services.

- a. Facilities for treatment or hospitalization.* In a facility where patients are examined and retained for treatment or hospitalization, the following must be provided:

(1) An examination room, separate from the reception room or office, with sufficient size to accommodate the veterinarian, assistant, patient and client.

(2) Nonporous tabletops, countertops and floor coverings which can be adequately cleaned and disinfected.

(3) The ability to house patients separately and maintain sanitary conditions.

(4) Appropriate separation of patients with known or suspected infectious and contagious diseases from patients not known to have such diseases in a manner that reasonably guards against transmission of disease.

(5) Provision for daily exercise of patients unless the primary enclosure is of sufficient size to provide exercise.

(6) Exercise areas that are cleaned a minimum of once in each 24-hour period and more frequently as may be necessary to reduce disease hazards and odors.

(7) A sanitary area for performing surgeries under sterile conditions. If sterile surgical procedures are performed on the premises, the veterinarian must maintain the following at all times:

1. Appropriate sterile surgical packs including drapes, sponges and instrumentation for use in each procedure.

2. For each sterile surgical procedure, equipment sterilized and surgical packs properly prepared for sterilization sufficient to kill microorganisms.

3. Clean attire, masks, and gloves for use in any sterile procedure.

(8) Oxygen and equipment necessary to administer oxygen to the types of patients treated in the facility.

(9) Capability to provide diagnostic radiological images in the facility or through an outside facility.

(10) Provision for laboratory and pharmaceutical services in the facility or through another commercial facility.

b. Facilities for services. Veterinary service facilities where patients are only examined and/or provided vaccinations must provide the following:

(1) An examination room, separate from the reception room or office, with sufficient size to accommodate the veterinarian, assistant, patient and client.

(2) Nonporous tabletops, countertops and floor coverings which can be adequately cleaned and disinfected.

(3) A secure and sanitary area for the storage of instruments and medications.

(4) Cooling/heating equipment for the storage of medications and immunization products.

(5) Capability to provide diagnostic radiological images in the facility or through an outside facility.

(6) Provision for laboratory and pharmaceutical services in the facility or through another commercial facility.

c. Mobile clinics. Mobile clinics are self-contained units for small animal, nonlivestock or nonpoultry patients and shall be equipped with the following:

(1) Hot and cold water.

(2) Nonporous tabletops, countertops and floor coverings which can be adequately cleaned and disinfected.

(3) An adequate power source for diagnostic equipment.

(4) A collecting tank for disposal of waste materials.

(5) Adequate lighting.

(6) Adequate heating, cooling and ventilation.

(7) Sterile instrumentation which meets the requirements of the level of surgery to be performed.

(8) Separate compartments for the transportation or holding of patients.

(9) A secure and sanitary area for the storage of instruments and medications.

(10) Cooling/heating equipment for the storage of medications and immunization products.

d. House/farm call units. House/farm call units are not self-contained units and must be equipped with or have access to all of the following:

(1) Water.

(2) Cooling/heating equipment for the storage of medications and immunization products.

(3) A secure and sanitary area for the storage of instruments and medications.

e. Emergency veterinary hospitals. “Emergency veterinary hospital” means an animal hospital which provides emergency treatment to an ill or injured patient. Any facility advertising as an emergency facility shall have a veterinarian and appropriate support staff on the premises during the hours of operation. Any facility which advertises using phrases similar or identical to “24-hour emergency veterinary hospital,” “Emergency,” “Open 24 hours,” or “Day or night care” must have treatment services continuously available.

12.5(2) Safety and sanitation standards. A veterinary facility must have a safe and sanitary environment that:

a. Protects the health of the patients and guards against the transmission of infection.

b. Provides for proper routine disposal of waste materials in compliance with all applicable local, state, and federal laws and regulations and for proper disposal of hypodermic devices, sharps and biomedical waste. Any person who is authorized to use hypodermic devices and sharps shall dispose of them in accordance with applicable local, state and federal regulations. Biomedical waste should be disposed of in accordance with applicable local, state and federal regulations.

c. Provides for proper sterilization or sanitation of all equipment used in diagnosis, treatment or surgery.

d. Ensures the maintenance of proper temperature and ventilation of the indoor facility.

e. Provides adequate lighting appropriate for the task being performed.

f. Includes legal and sanitary methods for the disposal or storage of deceased patients.

g. Meets the standards for radiological procedures as set by the Iowa department of public health.

12.5(3) Resources. A library of current journals or textbooks, or Internet access which provides readily accessible reference materials shall be available.